

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Boris Fuks et al.,

Application No.: 10/524,668

Filed: March 8, 2006

For: DEVICES AND METHODS FOR DETECTING
AMNIOTIC FLUID IN VAGINAL
SECRECTIONS

Confirmation No.: 1541

Art Unit: 1641

Examiner: Christopher L. Chin

**DECLARATION OF MICHAEL FRIEDMAN REGARDING MICROORGANISM
DEPOSITS IN ACCORDANCE WITH 37 C.F.R. §§ 1.801-1.809**

I, Michael Friedman do hereby declare and state as follows:

1. I am an inventor of the above-identified patent application.
2. The microorganisms identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 were deposited on May 22, 2003 in the Russian National Collection of Industrial Microorganisms (VKPM) Depository FGUPGOSNIIGitika, Russia 117545 Moscow, 1 Dorozhny proezd 1, an International Depositary Authority recognized under the Budapest Treaty.
3. The microorganisms identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 have been accepted for deposit under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
4. On information and belief, access to the microorganism deposits identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94

will be afforded during the pendency of this application to the Commissioner of Patent and Trademarks, or to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.114 and 35 U.S.C. § 122.

5. On information and belief, the microorganism deposits identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 will be released to the public irrevocably and without restriction upon the grant of a United States patent on this application.

6. On information and belief, the microorganism deposits identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 will be maintained at the above-mentioned public depository for a period that is at least: (a) 30 years from the date of the deposit(s), (b) the enforceable life of any patent issuing from this application, or (c) a period of five years after the date of the most recent request for furnishing a sample of biological material, whichever is longest.

7. On information and belief, the viability of VKPM H-92, VKPM H-93, and VKPM H-94 was tested on June 2005, and VKPM H-92, VKPM H-93, and VKPM H-94 were found to be viable on that date.

8. Should any of the microorganism deposits identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 become either nonviable or nonreplicable, it shall be replaced.

9. VKPM H-92, VKPM H-93, and VKPM H-94 was in the Applicant's possession at the time of filing the above-identified application.

10. A true copy of the original deposit receipt for the microorganism deposit identified by the International Depositary Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM H-94 is attached to this Statement, as Exhibit 1.

Declaration Regarding Microorganism Deposits

Application No. 10/524,668
(Confirmation No. 1541)

11. I declare that all statements made herein are based on personal knowledge or upon information and belief and are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: 5/19/09

Respectfully submitted,

Friedman
Signed Name

Michael Friedman
Printed Name

Attachment:

Exhibit 1: True copy of deposit receipt for microorganism deposit International
Depository Authority Accession Nos. VKPM H-92, VKPM H-93, and VKPM
H-94.

Appendix 3
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Budapest treaty on the international
recognition of the deposit of microorganisms
for the purposes of patent procedure

To
N-DIA, INC.,
30E. 20th Street, Suite 501
New York NY 10003
USA
name and address
of depositor

INTERNATIONAL FORM
receipt in the case of an original deposit
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

I. IDENTIFICATION OF THE HYBRIDOMA CELL LINES

Identification reference given by the
DEPOSITOR

Hybridoma Cell Lines N271

Accession number given by the
INTERNATIONAL DEPOSITARY-
AUTHORITY:
VKPM H-93

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ a scientific description

producer of monoclonal antibodies N271

Application: preparation of diagnostic device for
ruptures of fetal membranes

☐ a proposed taxonomic designation
(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,
which was received by it on 22.05.2003 (date of original deposit)

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary
Authority
on (date of original deposit) and a request to convert
the
original deposit to a deposit under the Budapest Treaty was received by it on
(date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depositary
FGUPGOSNIIGtika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature (s) of person(s) having the
power to represent the International

Authority or authorized official(s):
Date: Sineoky S.P. Director VKPM



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I. IDENTIFICATION OF THE HYBRIDOMA CELL LINES

Identification reference given by the
DEPOSITOR

Hybridoma Cell Lines N52

Accession number given by the
INTERNATIONAL DEPOSITARY
AUTHORITY:
VKPM H-92

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ a scientific description

producer of monoclonal antibodies N52

Application: preparation of diagnostic device for
ruptures of fetal membranes

☐ a proposed taxonomic designation
(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,
which was received by it on 22.05.2003. (date of original deposit)

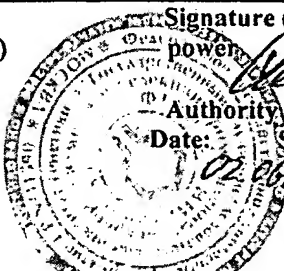
IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary
Authority
on (date of original deposit) and a request to convert
the
original deposit to a deposit under the Budapest Treaty was received by it on
(date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depositary
FGUPGOSNIIGtika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature (s) of person(s) having the
power to represent the International
Authority or authorized official(s):
Date: Sineoky S.P. Director VKPM
02.06.03



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To
N-DIA, INC.,
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of depositor

INTERNATIONAL FORM
receipt in the case of an original deposit
issued pursuant to Rule 7.1 by the
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I. IDENTIFICATION OF THE HYBRIDOMA CELL LINES

Identification reference given by the
DEPOSITOR

Hybridoma Cell Lines N42

Accession number given by the
INTERNATIONAL DEPOSITARY-
AUTHORITY:
VKPM H-94

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ a scientific description

producer of monoclonal antibodies N42
Application: preparation of diagnostic device for
ruptures of fetal membranes

☐ a proposed taxonomic designation
(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,
which was received by it on 22.05.2003 (date of original deposit)

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary
Authority
on (date of original deposit) and a request to convert
the
original deposit to a deposit under the Budapest Treaty was received by it on
(date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depositary
FGUPGOSNIIGtika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature (s) of person(s) having the
power to represent the International

Authority or authorized official(s):
Sineoky S.P. Director VKPM

Date: 02.06.03



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Budapest treaty on the international
recognition of the deposit of microorganisms
for the purposes of patent procedure

To
N-DIA, INC.,
30E.20th Street,Suite 501
New York NY 10003
USA

name and address of the party
to whom the viability statement
is issued

INTERNATIONAL FORM
VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR

N-DIA, INC

II. IDENTIFICATION OF THE

Hybridoma

Accession number given by the
INTERNATIONAL DEPOSITARY
AUTHORITY

VKPM H-92

Date of deposit

22. 05. 2003

III. VIABILITY STATEMENT

The viability of the hybridoma cell lines identified under above was tested
On June 2005. On that date the said hybridoma cell lines was viable

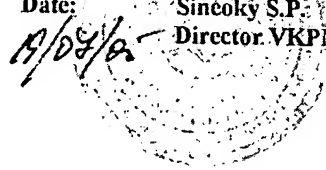
V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depositary
FGUPGOSNIIGenetika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature (s) of person(s) having the
power to represent the International

Authority or authorized official(s):

Date: 19/05/05 Sincoky S.P.
Director VKPM



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Budapest treaty on the international
recognition of the deposit of microorganisms
for the purposes of patent procedure

To
N-DIA, INC.,
30E.20th Street,Suite 501
New York NY 10003
USA
name and address of the party
to whom the viability statement
is issued

INTERNATIONAL FORM
VIABILITY STATEMENT
issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR

N-DIA, INC

**II. IDENTIFICATION OF THE
Hybridoma**

Accession number given by the
INTERNATIONAL DEPOSITARY
AUTHORITY
VKPM H-93
Date of deposit
22. 05. 2003

III. VIABILITY STATEMENT

The viability of the hybridoma cell lines identified under above was tested
On June 2005. On that date the said hybridoma cell lines was viable

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depositary
FGUPGOSNIIGenetika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature (s) of person(s) having the
power to represent the International

Authority or authorized official(s):
Date: Sineoky S.P.
Director VKPM

Sineoky
19/07/05

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Budapest treaty on the international
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To
N-DIA, INC.,
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USA
name and address of the party
to whom the viability statement
is issued

INTERNATIONAL FORM
VIABILITY STATEMENT
issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR

N-DIA, INC

II. IDENTIFICATION OF THE

Hybridoma
Accession number given by the
INTERNATIONAL DEPOSITARY
AUTHORITY
VKPM H-94
Date of deposit
22. 05. 2003

III. VIABILITY STATEMENT

The viability of the hybridoma cell lines identified under above was tested
On May 2003. On that date the said hybridoma cell lines was viable

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Russian National Collection
of Industrial Microorganisms (VKPM)
Depository
FGUPGOSNIIGenetika
Address: Russia 117545 Moscow
1 Dorozhny proezd 1

Signature(s) of person(s) having the
power to represent the International

Authority or authorized official(s):

Date: 02.06.03 Sineoky S.P.
Director VKPM

